REMARKS

The present invention provides a method for the once daily administration of a phenidate drug, especially *d-threo*-methylphenidate or a pharmaceutically acceptable salt. It will be appreciated that methyl phenidate, presently marketed in dl form under the trademark Ritalin,® must be administered two or more times a day. As explained in the present specification, such administration is quite inconvenient, especially for children and adolescents who must take a dose at school, and can lead to abuse. This is **not** a circumstance which is appropriately dealt with by providing the drug in sustained release form in that it is believed that the onloading and offloading of the drug is related to its therapeutic profile. To the contrary, it is desired to effect a pulsatile pattern of administration, as is experienced when the drug is taken at two times during the day.

A dosage form and method of administration has now been developed which permits the once daily administration of drug, but which gives rise to plasma levels of drug in patients which reflect pulsatile administration. That is, the present dosage forms effect two or more effectively separate administrations of the drug separated by a predetermined time period -- a pulsatile dosage form.

Claims 1 through 12 are pending in this application.

Claim 1 has been amended in view of the examiner's comments under section 112. Diseases amenable to treatment with phenidate drugs are known to persons skilled in the art and are set forth on pages 1 and 2 of the specification. Of course, other diseases or conditions which may be found to be benefitted from administration of phenidate drug will also be covered hereby. New claims 4 - 8 have been added to more completely claim the invention. No new matter has been added. See, e.g. page 8 of the specification.

The claims have been rejected under section 103 in view of U.S. Patent 5,593,694 Hayashida et al. However, Hayashida et al. is quite distinct from the present invention. The present invention is directed to pulsatile dosage forms and methods; Hayashida is directed to sustained release tablets. Sustained release is distinct from pulsatile release as set forth above. Indeed, Hayashida et al., if anything, teach away from the present invention. The examiner's suggestion that the claims "read on" sustained release formulations is not correct. Each claim requires temporal delay in the release of the phenidate drug from the first "spurt" to the second. In the case of claim 1, that delay is recited to be from about 2 to about 7 hours. Dependent claims recite at least about 3 or 4 hours. Hayashida et al. are directed to a totally different paradigm of pharmaceutical dosing such that the present invention

cannot be made out therefrom.

Reconsideration and allowance are respectfully requested.

Respectfully submitted,

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Date: November 22 1553

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